K003906

Bridger Biomed, Inc.

2430 N. 7th Street, Ste. 4, Bozeman, MT 59715
ph: 1-406-586-7666 or fax: 1-406-586-5665
-an ISO 9001 company-

JAN 26 2001

5.10 (k) Summary

Date:	December 18, 2000
Contact Person:	Bruce Ruefer
Classification Name:	Surgical Mesh
Common Name:	Surgical Mesh
Trade Name:	FluoroTex™ Surgical Mesh
Re:	Modification to K984197

The FluoroTex Surgical Mesh labeling is changed to add instructions for re-sterilization by either steam or Ethylene Oxide (EtO).

Summary of Performance:

Samples of the FluoroTex Surgical Mesh were re-sterilized 3 times with standardized steam and EtO sterilization methods. The samples were then tested according to written QC procedures and the results were compared to written specifications. All samples were found to meet specifications.

Conclusion:

Based on this study, re-sterilization three times by either steam or EtO methods does not adversely affect FluoroTex Surgical Mesh. Product labeling is thereby changed to reflect the capability of the FluoroTex Surgical Mesh to be re-sterilized.

BGRuefer

Bruce G. Ruefer, President

12-18-2000

date

FluoroTex is a Trademark of Bridger Biomed Inc. and patent pending.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2001

Mr. Bruce G. Ruefer
President
Bridger Biomed, Inc.
2430 N. 7th Street, Suite 4
Bozeman, Montana 59715

Re: K003906
Trade Name: FluoroTex™ Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: December 18, 2000
Received: December 19, 2000

Dear Mr. Ruefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number: [redacted] K003906

Device Name: FluoroTex™ Surgical Mesh

Indications for Use: The FluoroTex™ Surgical Mesh intended use is for the repair of soft tissue and the reconstruction of hernias.

for Mark N Milkens

(Division Sign-Off)
Division of General Restorative Devices K003906
510(k) Number